2 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	February 15, 2012
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: courtney.smith@arthrex.com
Trade Name	***Arthrex BioComposite GraftBolt***
Common Name	Screw, Fixation, Bone
Product Code -Classification Name *CFR*	**HWC** – Screw, fixation, bone **MAI** – Fastener, fixation, biodegradable **21 CFR 888.3030:** Single /multiple component metallic bone fixation appliances & accessories
Predicate Device	*K093912, K103060:* Arthrex Tibial GraftBolt *K112040:* Arthrex BioComposite Transfix *K071177:* Arthrex BioComposite Interference Screws
Purpose of Submission	This **special 510(k)** premarket notification is submitted to obtain clearance for the BioComposite GraftBolt, which is a line-extension of the Arthrex Tibial GraftBolt (K093912, K103060).
Device Description and Intended Use	The ***Arthrex BioComposite GraftBolt*** consists of a pre-packaged mating sheath and a screw pair offered in various sizes. The ***Arthrex BioComposite GraftBolt*** is intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone during cruciate ligament reconstruction procedures.
Substantial Equivalence Summary	The ***Arthrex BioComposite GraftBolt*** is substantially equivalent to the Arthrex Tibial GraftBolt (K093912, K103060) in which the basic features, and intended uses are the same. The biocomposite material is the same material used in the Arthrex BioComposite Transfix (K112040) and

	BioComposite Interference Screws (K071177). Any differences between the *BioComposite GraftBolt* and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness. The submitted degradation and biomechanical testing data demonstrates that the ultimate load strength of the proposed devices meets or exceeds the minimum acceptance criteria. Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the ***Arthrex BioComposite GraftBolt*** is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

MAR 2 0 2012

Re: K120540
Trade/Device Name: Arthrex BioComposite GraftBolt
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: March 6, 2012
Received: March 8, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number: _____

Device Name: ***Arthrex BioComposite GraftBolt***

Indications For Use:

The ***Arthrex BioComposite GraftBolt*** is intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone during cruciate ligament reconstruction procedures.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120540